SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NexGard 68 mg chewable tablets for dogs > 10–25 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:

NexGard	Afoxolaner (mg)
chewable tablets for dogs > 10-25 kg	68

Excipients:

Qualitative composition of excipients and other constituents
Maize starch
Soy protein fines
Beef braised flavouring
Povidone (E1201)
Macrogol 400
Macrogol 4000
Macrogol 15 hydroxystearate
Glycerol (E422)
Triglycerides, medium-chain

Mottled red to reddish brown, rectangular shaped chewable tablets (for dogs > 10–25 kg).

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of flea infestation in dogs (*Ctenocephalides felis* and *C. canis*). The veterinary medicinal product provides immediate and persistent killing activity for at least 5 weeks. The product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

Treatment of tick infestation in dogs (*Dermacentor reticulatus*, *Ixodes ricinus*, *Ixodes hexagonus*, *Rhipicephalus sanguineus*, *Hyalomma marginatum*). The veterinary medicinal product provides immediate and persistent killing activity for one month.

Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.

Treatment of demodicosis (caused by *Demodex canis*).
Treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*).
Treatment of ear mite infestations (caused by *Otodectes cynotis*).

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Parasites need to start feeding on the host to become exposed to afoxolaner; therefore the risk of the transmission of parasite borne diseases cannot be excluded.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infestation with fleas, ticks or mites should be considered, and these should be treated as necessary with an appropriate product.

3.5 Special precautions for use

Special precautions for safe use in the target species:
In the absence of available data, treatment of puppies less than 8 weeks of age and/or dogs less than 2 kg bodyweight should be based on a benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
To prevent children from getting access to the veterinary medicinal product, remove only one chewable tablet at a time from the blister. Return the blister with the

remaining chewable tablets into the carton. In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.

Wash hands after handling the veterinary medicinal product.
Special precautions for the protection of the environment
Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders[1] (vomiting[2], diarrhoea[2]) Lethargy[2], anorexia[2] Pruritus[2]Neurological disorders (convulsion[2], ataxia[2], muscle tremor[2]).

[1] Mild.
[2] Mostly self-limiting and of short duration.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used in pregnant and lactating dogs.
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects.

Fertility:
Can be used in breeding females.
The safety of the veterinary medicinal product has not been established in breeding males. In breeding males, use only according to the benefit-risk assessment by the responsible veterinarian.
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects, or any adverse reactions on the reproductive capacity of males.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

Dosage:
The veterinary medicinal product should be administered at a dose of 2.7 to 7 mg/kg bodyweight of afoxolaner in accordance with the following table:

Bodyweight of dog (kg)	**Strength and number of chewable tablets to be administered**			
	NexGard 11 mg	NexGard 28 mg	NexGard 68 mg	NexGard 136 mg
2–4	1			
> 4–10		1		
> 10–25			1	
> 25–50				1

For dogs above 50 kg bodyweight, use an appropriate combination of chewable tablets of different/same strengths.
To ensure a correct dosage, body weight should be determined as accurately as possible.
The chewable tablets should not be divided. Underdosing could result in ineffective use and may favour resistance development.

Method of administration:
The tablets are chewable and palatable to most dogs. If the dog does not accept the tablets directly they may be administered with food.

Treatment schedule:
Treatment of flea and tick infestations:
Monthly intervals throughout the flea and/or tick seasons, based on local epidemiological situations and the animal's lifestyle.

Treatment of demodicosis (caused by Demodex canis):
Monthly administration of the veterinary medicinal product until two negative skin scrapings are obtained one month apart. Severe cases may require prolonged monthly treatments. As demodicosis is a multi-factorial disease, where possible, it is advisable to also treat any underlying disease appropriately.

Treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*):
Monthly administration of the veterinary medicinal product for two consecutive months. Further monthly administration may be required based on clinical assessment and skin scrapings.

Treatment of ear mite infestations (caused by *Otodectes cynotis*):
A single dose of the veterinary medicinal product should be administered. A further veterinary examination one month after the initial treatment is recommended as some animals may require a second treatment.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions were observed in healthy Beagle puppies over 8 weeks of age when treated with 5 times the maximum dose repeated 6 times at intervals of 2 to 4 weeks.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53BE01.

4.2 Pharmacodynamics

Afoxolaner is an insecticide and acaricide belonging to the isoxazoline family. Afoxolaner acts at ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarines. The selective toxicity of afoxolaner between insect/acarines and mammals may be inferred by the differential sensitivity of the insect/acarines' GABA receptors versus mammalian receptors.

Afoxolaner is active against adult fleas as well as several tick species such as *Dermacentor reticulatus* and *D. variabilis, Ixodes ricinus, Ixodes hexagonus* and *I. scapularis, Rhipicephalus sanguineus, Amblyomma americanum, Haemaphysalis longicornis, and Hyalomma marginatum*.

The veterinary medicinal product kills fleas within 8 hours and ticks within 48h.

The veterinary medicinal product kills fleas before egg production and therefore prevents household contamination.

4.3 Pharmacokinetics

After oral administration in dogs, afoxolaner was shown to have high systemic absorption following administration. The absolute bioavailability was 74 %. The mean maximum concentration (C_{max}) was 1,655 ± 332 ng/ml in plasma at 2–4 hours (T_{max}) after a 2.5 mg/kg afoxolaner dose.

Afoxolaner distributes into tissues with a volume of distribution of 2.6 ± 0.6 l/kg and a systemic clearance value of 5.0 ± 1.2 ml/hr/kg. The terminal plasma half-life is

approximately 2 weeks in most dogs; however, half-life of afoxolaner can differ between dogs (e.g. in one study, $t_{½}$ in Collies at 25 mg/kg bodyweight was up to 47.7 days) with no effect on safety. *In vitro* experiments demonstrated that P-glycoprotein efflux does not occur, confirming that afoxolaner is not a substrate for the P-glycoprotein transporters.

Afoxolaner in the dog is metabolised to more hydrophilic compounds and then eliminated. The metabolites and parent compound are eliminated from the body via urinary and biliary excretion with the majority eliminated in the bile. No evidence of enterohepatic recycling has been observed.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is individually packaged in thermoformed laminated PVC blisters with paper-backed aluminium (PVC/Alu).

Cardboard box with 1 blister of 1, 3 or 6 chewable tablets or 3 blisters of 6 chewable tablets or 15 blisters of 1 chewable tablet.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 04491/5030

8. DATE OF FIRST AUTHORISATION

11 February 2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

September 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

Gavin Hall
Approved: 12 December 2024